FAS

UNITED STATES DEPARTMENT OF AGRICULTURE
INTERNATIONAL REGULATIONS AND STANDARDS &
PROCESSED PRODUCTS AND TECHNICAL REGULATIONS DIVISIONS

INTER-AGENCY CLEARANCE REQUEST
WTO SPS/TBT AGRICULTURAL NOTIFICATION
U.S. GOVERNMENT COMMENTS ON FOREIGN NOTIFICATIONS

STANDING CLEARERS

Agency	Name	Phone	Fax	Email
USTR, SPS Affairs	Julia Doherty	202-395-9559	202-492-6402	Julia_Doherty@ustr.eop.gov
USTR, TBT Affairs	Jennifer Stradtman			Jennifer A_Stradtman@ustr.eop.gov
USTR, Assoc. General Counsel	Sloan Strickler	202-395-6164	202-395-5674	Sloan_Strickler@ustr.eop.gov
USTR, Assoc. General Counsel	Ron Baumgarten	202-395-9583	202-395-5674	Ronald_Baumgarten@ustr.eop.gov
EPA	Daniella Taveau	202-564-0530		Taveau.Daniella@epamail.epa.gov
DOC/ITA (SPS)	Adam Boltik	202-482-0357	202-482-6097	Adam.Boltik@trade.gov
DOC/ITA (TBT)	Bryan O'Byrne	202-482-0705	202-482-6097	Bryan_O'Byrne@ita.doc.gov
DOC/NIST	NIST			ncsci@nist.gov
FDA	Mark Abdoo	301-796-8964		mark.abdoo@fda.hhs.gov
FDA	Anne Kirchner	240-402-0291		anne.kirchner@fda.hhs.gov
FDA/CFSAN	Cory Bryant	240-402-1586		cory.bryant@fda.hhs.gov
FDA/CFSAN	Jeffrey Read	240-402-1935	301-436-2618	Jeffrey.Read@fda.hhs.gov
FDA/CFSAN	Debbie Subera-Wiggin	240-402-1726	301-436-2618	debbie.subera-wiggin@fda.hhs.gov
FDA/CVM	Jon Scheid			John.scheid@fda.hhs.gov
FDA/CVM	Ashley Steel			Ashley.Steel@fda.hhs.gov
STATE (TBT) Issues	Shelbie Legg			LeggSC@state.gov
STATE (SPS issues)	Travis Coberly			CoberlyT@state.gov
USDA/FAS	Bob Macke	202-720-4434		robert.macke@fas.usda.gov
FAS	Marianne McElroy	202-720-9408	202-690-0677	Marianne.McElroy@fas.usda.gov
FAS	Laura Anderson	202-720-0607	202-720-0433	Laura.Anderson@fas.usda.gov
FAS	Lori Tortora	202-720-0634	202-720-0433	Lori.Tortora@fas.usda.gov
APHIS	Patricia Abad	202-720-8665		patricia.abad@aphis.usda.gov
APHIS	Lynn Alfalla	202-720-6315		Lynn.Alfalla@aphis.usda.gov
APHIS	Russ Caplen	202-720-2161		Russell.T.Caplen@aphis.usda.gov
APHIS	Jay Mitchell	202-720-4785	202-690-2861	Jay.k.mitchell@aphis.usda.gov
APHIS	Eric S. Nichols	202-720-3456		Eric.S.Nichols@aphis.usda.gov
USDA/FSIS	FSIS Mailbox			Sps/tbtrequests/submissions@fsis.usda.gov
FSIS	Shannon McMurtrey			Shannon.McMurtrey@fsis.usda.gov
FSIS	Richard Brown	202-690-3182	202-720-4929	Richard.Brown@fsis.usda.gov
FSIS	Mary Stanley			Mary.Stanley@fsis.usda.gov

USDA/AMS Dorian LaFond 690-4944 202-720-0016 Dorian.LaFond@usda.gov

ISSUE SPECIFIC CLEARERS

Date of Last Update: January 27, 2016

Attached are draft comments on WTO Notification G/TBT/N/BRA/648 on pesticides. Comments are sought from agencies so that the official comments accurately reflect the position of the U.S. Government. Clearance is assumed if no comments are received.

Comments must be received by COB January 29, 2016

Please send comments to

Email: becxi.sanchez@fas.usda.gov
Phone: 202.690.0607
Fax: 202.690.0677

1. Action requested:

A. Post is requested to deliver U.S. comments below beginning in paragraph 2. Delivery is to be made as soon as possible to the authorities listed below:

- National Institute of Metrology, Quality and Technology – INMETRO
  Telephone: +(55) 21 2563.2840
  Telefax: +(55) 21 2563.5637
  Email: barreirastecnicas@inmetro.gov.br
  Web-site: http://www.inmetro.gov.br/barreirastecnicas

  Comments on this Draft Regulation shall be sent to:
  http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=22736

- Brazilian Health Surveillance Agency – ANVISA

B. Please report back to FAS/OASA/PPTRD with the date and to whom the comments were delivered (including names, organizations, addresses, telephone and fax numbers). If no immediate response is received from the country, Post will periodically provide PPTRD with updates on the implementation status and changes to the WTO measure until U.S. concerns are resolved.

2. The following are the U.S. comments:

BEGIN U.S. COMMENTS:

The United States appreciates the opportunity to provide comments on WTO Notification G/TBT/N/BRA/648 regarding Brazil's "Draft Technical Resolution n° 87, October 2nd 2015,

regarding the pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration."

The United States has the following comments to offer:

Chapter I, General Provisions:

The United States shares Brazil public policy **objectives** of the proposed risk management approach for substance of concern: protection of human health and the environment. However, with the proposed two- step process chemicals having an unacceptable hazard profile are discounted from registration without proceeding to the risk assessment step. We encourage Brazil to further develop this approach and would like to share the following recommendations:

- We encourage Brazil to regulate on the basis of risk of a chemical. Focusing on hazard only, rather conducting a risk assessment that incorporates the hazard, exposure, and characteristics of the pesticide, leads to conservative assumptions that could prohibit the use of necessary pest management tools.

- We note that classification systems for all major endpoints are described and mirror those of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). GHS can be viewed as a process whereby a level of concern over hazard properties can be consistently described. We would encourage the use of a full and transparent weight and strength of the evidence in arriving at a given classification decision.

- The current criteria indicate that certain classification outcomes preclude registration in Brazil. We would encourage consideration of limitations of this effect to chemicals and endpoints where there is reasonable concern over the lack of a threshold, or in situations where a threshold can be demonstrated and human safety has been assessed and protected through a risk assessment. It is therefore not advisable to equate Classifications 1a and b for carcinogenicity and reproductive toxicity with an automatic ban on registration, for example.

- Regarding the Acceptable Operator Exposure Level (AOEL), the draft text of the measure indicates that oral absorption should be taken into account when the AOEL is derived. We would recommend the provision of additional guidance on this process.

- Article 31 refers to studies for clarifying the toxicological action form and/or mechanism for a better interpretation of adverse effects. We would advise to broaden the scope if this provision to include all adverse effects, for example, tumors, developmental and reproductive effects regardless of category. In this regard, categorization may be appropriate for labeling but not for exclusion criteria for registration as it does not take into account scientific understanding gained by the studies described within the draft text.

Chapter II and Annex I - Active Ingredients, Data Requirements:

Would Brazil make use of any additional data provided in arriving at a judgment classification decisions in particular for carcinogenicity and reproductive toxicity?

Regarding Carcinogenicity and Reproduction and Development, has Brazil considered additional use of toxicokinetics, exposure, and dose-response criteria? The criteria included in the draft text may be adequate for classification labeling, however it may raise questions regarding appropriateness for cut offs when risk assessment can be conducted for all classification levels based on identified data.

Studies related to absorption, distribution, metabolism, and excretion (ADME) including in vitro, we note there is an indication of the need to compare in vitro metabolism across species (including human), criteria used in international practice. However has Brazil also considered cases where there is no scientific (OECD or other) guideline describing how a data requirement should be met? In these cases international practice in the area shows that the need for the data can be waived. For example, since intentional human dosing of agrochemicals is not possible, a meaningful comparison of in vivo products of metabolism cannot be made between humans and test species.

Regarding endocrine disruption, we support the inclusion and further elaboration of the use of additional studies: immunological, endocrine, metabolites, route specific, which may be conducted after an initial evaluation of a database, for consideration when there is a need to clarify uncertainties.

Annex II, Section 12, Considerations on the mutagenicity tests, Subsection 12.2 indicates that *"If the in vitro study of chromosome damages shows positive or equivocal result an additional study to investigate in vivo chromosome damages should be conducted."* Would Brazil still accept a negative result in vitro for a formulated product?

Annex III, Section 4, Considerations on the mutagenicity studies, Subsection 4.1.d. indicates that *"If the in vitro study of chromosome damages required in item 2 and 3 shows negative or equivocal result the study to investigate the in vivo chromosome damage induction should be conducted"*. Could Brazil please clarify if the intention is to refer in this section to positive or equivocal results and the stated reference in the draft text may be due to a typographical error?

Annex IV, Classification, regarding carcinogenicity, has Brazil considered adding a "No Classification" row in the tables on carcinogenicity, pages 62/63 and on reproductive toxicity, page 65? This would helpfully outline circumstances where the strength of evidence is insufficient for classification and would be useful when distinguishing between Category 2 and No Classification.

Finally, we welcome the inclusion of the statement on agrochemicals, their components, and related items classified in category 2 which are not considered as carcinogenic and can be re-evaluated when additional and relevant information are available. In this regard we note that for agrochemicals an extensive and complete database is presented for registration, therefore it is possible that chemicals can be removed from consideration for classification based on the data presented. Should new data become available then a reclassification could be considered as stated in the draft text.

The United States thanks Brazil for its consideration of our comments.

END U.S. COMMENTS